

# BARRIERS TO BLACK WOMEN'S PARTICIPATION IN CANCER CLINICAL TRIALS

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This study examines attitudes that may deter black women from participating in cancer research. Subjects were recruited from women who did not respond to the initial recruitment mailing for the Women's Health Initiative. Each subject was administered a 7- to 10-minute telephone survey. One third (29) of the 80 subjects were black.

Fifty-six percent of black women and 71% of white women had positive attitudes toward cancer clinical trials. More than 80% of the women surveyed agreed that clinical research benefits society and increases medical knowledge. However, almost one third of the black women agreed that scientists cannot be trusted while only 4% of whites responded similarly. Additionally, 29% of black women agreed that researchers did not care about them compared with 14% of white women. Only 28% of black women felt that clinical research in the United States was ethical, and 37% had a preference to be treated by a black scientist compared with 2% of whites. Controlling for other covariates, black women had more negative attitudes overall to clinical trials than white women.

These findings support the likelihood that barriers exist for the participation of blacks and other minorities in clinical research. These barriers may impact the involvement of black women in cancer clinical trials. Improving trust and creating a perception of a caring attitude from investigators are important to overcoming these barriers. The inclusion of more black scientists as leaders of cancer clinical trials also may help improve these participation rates. (*J Natl Med Assoc.* 1997;89:721-727.)

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**Key words:** blacks ♦ clinical trials ♦ recruitment

Cancer is the second most common cause of death for US women. For minority women, cancer remains

a major health problem. In 1992, a total of 245,740 female deaths were attributed to cancer, with 10.7% of these deaths occurring among black women.<sup>1</sup> In 1996, an estimated 28,840 black women will die from cancer.<sup>2</sup> Despite large-scale community education and screening efforts in the past decade, cancer mortality has remained steady. Efforts in the urban minority community have been especially ineffective, contributing to a decrease in cancer survival for this community. Deaths from malignant neoplasms among blacks is roughly 20% higher than for whites.<sup>3</sup> In addition, the mean age at death is younger for blacks than for whites. The differential case fatality rates between blacks and whites can be traced to several

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factors.<sup>4,5</sup> One factor may be the poor participation of blacks in clinical trials of cancer prevention.

### ACCRUAL FOR CANCER TRIALS

Many of the trials sponsored by the National Institutes of Health have been sorely deficient in participation by minorities, and many of the new treatments have not been studied in adequate numbers of minorities. A study by Hunter et al<sup>6</sup> showed that of the participants in the Community Clinical Oncology Program sponsored by the National Cancer Institute, only 4% were black, and of those who participated in the Surveillance, Epidemiology, and End Results program sponsored by the National Cancer Institute, only 8% were black. Research by Millon-Underwood and colleagues<sup>7</sup> showed that while blacks know about cancer clinical trials, they lack the desire to enter into them. Therefore, blacks may be receiving less benefit from and poorer access to more advanced cancer treatment due to their absence from these study cohorts.

Blacks are underrepresented in other clinical research studies. A study by Svensson<sup>8</sup> showed that 23 of 35 studies had a lower percentage of black participation than that present in the community where recruitment took place. The lack of black participation and the poor participation by other ethnic groups hurts the generalizability of the research to the entire population. In previous reviews, Johnson<sup>9-11</sup> has discussed the methodological issues that favor using homogenous samples in clinical trials. His reviews have shown that it is difficult to generalize the results of research that excludes minorities, includes them in inadequate numbers, or does not sufficiently report the demographics of the sample. More information is needed to understand the barriers to minority participation in cancer clinical trials. This information would allow the development of strategies to adequately recruit and retain larger numbers of black participants.

To better understand this problem, we examined the barriers to participation in a large-scale multicentered trial of a cancer prevention therapy (ie, low-fat diet) for women. Our study evaluates barriers to the primary recruitment strategy, which was a mass mailing. The specific aims of our study included the following:

- to compare attitudes toward participation in cancer clinical trials for black and white subjects,
- to compare attitudes toward cancer screening and cancer prevention between black and white

subjects,

- to discover the process by which black women decide whether to participate in cancer clinical trials, and
- to assess whether blacks are more likely to participate in research that is conducted by black researchers.

### METHODS

Two hundred forty-eight subjects from among the nonrespondents to an initial recruitment mailing for the Women's Health Initiative (WHI) were contacted. The WHI is a national multicentered clinical trial to determine the efficacy of low-fat diets, hormonal replacement therapy, and vitamin D/calcium supplementation to prevent coronary heart disease, breast cancer, colorectal cancer, and osteoporosis in postmenopausal women. The WHI sends mailings to mature women aged 50 to 79 years using an introductory letter and return-addressed postcard. Commercially purchased mailing lists are used for this recruitment effort with 20% of respondents expected to be black women. The WHI has a broad, intensive recruitment that provides an opportunity to address the question of resistance to participation in clinical trials. The nonrespondents to the WHI recruitment efforts were contacted and asked to participate in our telephone survey. The survey instrument assessed their attitudes toward clinical research, cancer clinical trials, their health status, and basic demographics.

Each month, a list of women who did not respond to the initial WHI mailing was formulated. This list was used to contact these nonrespondents and ask them to participate in our study. Next, these women were contacted by telephone, screened for eligibility to enter our study, and administered a 7- to 10-minute, 33-item telephone survey. The eligibility criteria were as follows:

- not currently participating in any other clinical trial,
- able to speak English fluently, and
- no history of terminal illness, psychiatric disorder, or cognitive impairment.

African-American women were oversampled to obtain appropriate representation in this group by targeting women according to zip code and municipal information.

The survey instrument consisted of items about demographics, health status, religion, and attitudes toward participation in clinical trials. Demographic

information included age, race, years of schooling completed, income, religion, and marital status. To assess health status, a five-point ordinal scale measuring general quality of life was used. Religion was assessed by having subjects pick from the following categories: Protestant, Catholic, Jewish, Islamic, or other.

Questions to assess attitudes toward participation in clinical trials were adapted from a survey by Millon-Underwood et al<sup>7</sup> with responses based on a five-point Likert scale ranging from strongly agree to strongly disagree. These questions were used to develop the "Positive Attitude Toward Clinical Trials" subscale (PATCT) and the "Negative Attitude Toward Clinical Trials" subscale (NATCT). The scoring was done by summing the values for each question. The PATCT values were determined by giving one point for each level of agreement with positive statements about clinical trials. The NATCT values were determined by giving one point for each level of agreement with negative statements about clinical trials. Higher scores indicated more positive or negative attitudes toward clinical trials, respectively. The questionnaire also included items based on a five-point Likert scale asking participants' preference to be treated by a black scientist, their preference to be treated by a Latino scientist, whether transportation was a problem for research participation, and whether they considered research in the United States ethical.

For analysis, univariate results were calculated for all variables. The PATCT and NATCT scores were treated as the main dependent variables. The selected independent variables were race, education, income, health status, a preference to be treated by a black scientist, and religion. Two of the 82 subjects who were neither black nor white were dropped from the analyses.

The bivariate associations of race (black/white) with each independent and dependent variable were assessed using the chi-squared test for nominal variables. Bivariate associations of the PATCT and NATCT score with each independent variable were assessed using a univariable linear regression. A multivariable linear regression analysis was performed to assess the association of race with PATCT score and race with NATCT score while controlling for possible confounders. Variables were selected from the bivariate associations for inclusion in the multivariable model. These variables were significantly associated with the two dependent variables at the  $P=.10$  level to correct for multiple testing.

Results were analyzed using SAS for Windows, Version 6.11.<sup>12</sup> The study was approved by the Institutional Review Board of the UMDNJ-New Jersey Medical School.

## RESULTS

Of the 80 women surveyed, the average age was 62 years (range: 37 to 86 years) (Table 1). Fifty-one (63.3%) were white, and 29 (36.8%) were black. Most were well-educated (65.3%); only 5% had not completed high school. While half were retired (55.1%), of those providing income data (57), more than two thirds (68.4%) had yearly incomes  $> \$25,000$ . More than one third (37.3%) were Protestant, with 26% Catholic, 12% Jewish, and 24% other. Most were in good or very good health (72%), with only seven (8.8%) respondents rating their health as poor or very poor. Fifty percent of the women surveyed were widowed, and 11.4% were currently married. More than 80% of the women surveyed had a private physician for their medical care, and only 1% of them used a hospital emergency room for medical care. Eighty-seven percent of the women had not previously taken part in a research study.

Several differences were evident between black and white women regarding their attitudes about clinical research. Almost one third (32.1%) of the black women agreed or strongly agreed that scientists cannot be trusted compared with only 4.1% of whites ( $P=.001$ ) (Table 2). However, more than one quarter (27.6%) of blacks strongly agreed or agreed with the statement, "It is better to be treated by a researcher" versus 6.1% of whites ( $P=.01$ ). When it came to their perception of researchers and whether researchers genuinely cared about them, 28.6% of the black women agreed or strongly agreed that researchers did not care about them while only 13.7% of white women chose this response; these differences did not reach statistical significance ( $P=.775$ ). Thirty-seven percent of black women compared with 2% of whites preferred to be treated by a black scientist ( $P=.014$ ).

Regardless of race, most women had positive attitudes toward research (55.6% for blacks and 70.6% for whites;  $P=.184$ ). Approximately 26% of the white women surveyed disagreed that by participating in clinical research they would have access to better care while 44.4% of the black women shared the same opinion. Also, both groups strongly agreed that participation in research was risky (56.9% of white and 60.7% of black women).

Table 1. Percent Distribution of Variables for Women Who Declined to Participate in Clinical Trials

Variable	No.*	Total %†	% Black (n=29)	% White (n=51)
Marital status				
Never married	10	12.7	10.3	14.0
Married	9	11.4	13.8	10.0
Widowed	40	50.6	41.4	56.0
Separated/divorced	20	25.3	34.5	20.0
Age				
<56 years	23	28.7	41.4	21.6
56 to 64 years	20	25.0	31.0	21.6
65 to 72 years	20	25.0	17.2	29.4
>72 years	17	21.3	10.3	27.5
Education				
<High school	4	5.1	3.6	6.0
High school graduate	23	29.5	32.1	28.0
Some college or technical school	20	25.6	21.4	29.4
College graduate	31	39.7	42.9	38.0
Religious affiliation				
Protestant	28	37.3	53.6	27.7‡
Catholic	20	26.7	10.1	36.2
Jewish	9	12.0	3.6	17.0
Other	18	24.0	32.1	19.2
Annual income				
≤\$25,000	18	31.6	36.0	28.1
≥\$25,000	39	68.4	64.0	71.9
Retired	43	55.1	46.4	60.0
Recently hospitalized	13	16.5	19.6	10.7
Who have taken part in a research study	10	12.7	13.8	12.0
Quality of health				
Very good/good	58	72.5	72.4	76.6
Fair	15	18.8	20.7	17.7
Poor/very poor	7	8.8	6.9	9.8
Totals	80	100	36.8	63.3

\*Maximum N=80. With the exception of income, when N=57, the number of missing cases for each variable ranges between 75 to 80.

†Percentages are based on valid cases. Total percent may not always equal 100% because of rounding.

‡Differences are statistically significant at  $P \leq .01$  based on chi-squared tests.

There were no racial differences among the subjects on whether research is enjoyable or allows one to socialize. There also was no notable difference regarding whether research was against their religion or whether transportation was a problem in participating in research trials. When questioned on whether research was morally wrong, 80% of the black women disagreed or strongly disagreed while 74.5% of whites shared the same opinion. Approximately 70% of all women surveyed believed that any patient should be able to participate in research as long as the patient was well-informed and gave consent.

When examining the associations with a negative attitude to clinical trials, black women scored 1.14

points lower than white women after controlling for possible confounders ( $P=.026$ ), indicating more negative attitudes (Table 3). Level of education also was found to be significant in the model after controlling for possible confounders. Those subjects who were more educated had 0.71 fewer points on the assessment of negative attitudes to clinical trials than those with less than a high school education ( $P=.01$ ). However, the number of women with positive attitudes was similar in both racial groups after controlling for possible confounders (Table 4.)

## CONCLUSION

Among women who did not respond to a mailed recruitment for a clinical trial, some important attitu-

Table 2. Percent Distribution of Agreement/Disagreement on Attitudinal Statements

Variable	Total %*	% Black	% White
1. Participation in clinical research benefits society			
Strongly agree/agree	87.0	89.3	86.0
Neither agree nor disagree	9.0	3.6	12.0
Disagree/strongly disagree	3.9	7.1	2.0
2. Participation will mean better care			
Strongly agree/agree	27.3	29.6	26.0
Neither agree nor disagree	40.0	25.9	48.0
Disagree/strongly disagree	32.5	44.4	26.0
3. Participation in research is risky			
Strongly agree/agree	58.2	60.7	56.9
Neither agree nor disagree	27.9	25.0	29.4
Disagree/strongly disagree	13.9	14.3	13.7
4. Researchers do not care about me			
Strongly agree/agree	19.0	28.6	13.7
Neither agree nor disagree	48.1	42.9	51.0
Disagree/strongly disagree	32.9	28.6	35.3
5. Participation in research is enjoyable			
Strongly agree/agree	20.0	16.0	22.0
Neither agree nor disagree	74.7	76.0	74.0
Disagree/strongly disagree	5.3	8.0	4.0
6. Participation in research allows me to socialize			
Strongly agree/agree	41.6	37.0	44.0
Neither agree nor disagree	52.0	51.9	52.0
Disagree/strongly disagree	6.5	11.1	4.0
7. Participation in research is against my religion			
Strongly agree/agree	3.8	3.5	3.9
Neither agree nor disagree	8.8	17.2	3.9
Disagree/strongly disagree	87.5	79.3	92.2
8. Participation in research is morally wrong			
Strongly agree/agree	2.6	4.0	2.0
Neither agree nor disagree	21.1	16.0	23.5
Disagree/strongly disagree	76.3	80.0	74.5
9. Transportation is a problem for people who participate			
Strongly agree/agree	34.7	30.8	33.3
Neither agree nor disagree	38.7	30.8	42.9
Disagree/strongly disagree	28.0	38.5	22.5
10. Scientists cannot be trusted			
Strongly agree/agree	14.3	32.1	4.1†
Neither agree nor disagree	48.1	39.3	53.1
Disagree/strongly disagree	37.7	28.6	42.9
11. Better to be treated by doctors who are researchers			
Strongly agree/agree	14.1	27.6	6.1†
Neither agree nor disagree	47.4	37.9	53.1
Disagree/strongly disagree	38.5	34.5	40.8
12. Prefer study headed by black scientist			
Strongly agree/agree	14.3	37.0	2.0†
Neither agree nor disagree	80.5	63.0	90.0
Disagree/strongly disagree	5.2	0.0	8.0

**Table 2. Percent Distribution of Agreement/Disagreement on Attitudinal Statements (continued)**

Variable	Total %*	% Black	% White
13. Prefer study headed by Latino scientist			
Strongly agree/agree	5.2	11.1	2.0
Neither agree nor disagree	85.7	74.1	92.0
Disagree/strongly disagree	9.1	14.8	6.0
14. Opinion of research in the United States as ethical or not			
Not Ethical	10.3	13.8	8.2
Ethical	39.7	27.6	46.9
Don't know or other responses	50.0	58.6	44.9

\*Total % may not always equal 100% because of rounding.

†Differences are statistically significant at  $P \leq .01$  based on chi-squared tests.

**Table 3. Associations With a Negative Attitude to Clinical Trials Controlling for Other Factors\***

Variables	Parameter Estimate	SE	P Value
Intercept	18.4830	0.9966	—
Race†	1.1415	0.5008	.026
Education‡	-0.7100	0.2623	.009
Marital status§	0.2052	0.5183	.693
Retired	-0.4568	0.4843	.349

Abbreviations: SE=standard error.

\* $R^2=0.1828$ ; adjusted  $R^2=0.1367$ .

†Race: 0=black; 1=white.

‡Education: 0=high school or less; 1=some college or greater.

§Marital status: 0=never married, separated, or divorced; 1=married or widowed.

||Retired: 0=no; 1=yes.

**Table 4. Associations With a Positive Attitude to Clinical Trials Controlling for Other Factors\***

Variables	Parameter Estimate	SE	P Value
Intercept	16.4081	1.0136	—
Race†	-0.0539	0.5092	.916
Education‡	-0.1243	0.2681	.644
Marital status§	0.0533	0.5263	.920
Retired	1.3237	0.4941	.009

Abbreviations: SE=standard error.

\* $R^2=0.0978$ ; adjusted  $R^2=0.0463$ .

†Race: 0=black; 1=white.

‡Education: 0=high school or less; 1=some college or greater.

§Marital status: 0=never married, separated, or divorced; 1=married or widowed.

||Retired: 0=no; 1=yes.

dinal differences were noted between black and white women. Black women were more likely to feel that clinical research was unethical, that researchers did not care about them, and that by participating in research, they would not have access to better care. Black women indicated that they would be more likely to participate if the researcher was also black. This study corroborates the findings of Harris et al<sup>13</sup> that African Americans fear clinical trials and lack trust in the medical system. Our findings also support the possibility that a major impediment for black participation in clinical research is a lack of trust. These attitudes may represent an individual's personal experience of racial inequity or result from centuries of institution-based mistreatment of the black community.

Furthermore, the inequities in the health-care system provide the black community with confirmation of the suspicions harbored against academic centers and other research institutions. The fact that one third of the black women agreed that researchers do not care about them demonstrates these suspicions. Furthermore, the mistreatment they experience in seeking health services has alienated many blacks, especially those who belong to the "working poor" class who earn too little to afford private insurance and too much to qualify for public assistance. This serves to promote increasing dissatisfaction with the medical system and serves to enhance the barriers that prevent many of them from participating in clinical trials.

This study does have some limitations. Only 80 subjects who agreed to complete the telephone questionnaire were analyzed. These subjects could have given systematically different answers from those who were not recruited. As a result, some of the responses that differ by race may be misleading. However, we suspect that our findings may be conservative in that nonparticipants in our study are likely to have even more negative attitudes toward clinical trials. Also, we did not systematically develop a weighting scheme for the PATCT and NATCT scores. Some questions may have been more predictive of a positive attitude than others and therefore should have been given a greater value in scoring. Despite these limitations, we feel this study provides evidence that certain specific attitudes affect the willingness to participate in clinical trials and that some of these attitudes differ between black and white women. More research is needed to explain these findings and develop ways to overcome the level of distrust that blacks have shown in this study.

Some strategies might alleviate some of these attitudinal barriers. First, to overcome the barrier of distrust, investigators could include influential community members in the planning stages of clinical trial recruitment. In doing so, the community leaders might help dispel some of the suspicion held by the black community. Second, inclusion of black investigators in leadership roles also can help alleviate some of the mistrust in the community. Third and perhaps most importantly, facilitating institutional change in a culturally competent manner that promotes the provision of needed health services for the black community can promote a better working relationship for future research.

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